

Applicants: Graham P. Allaway et al.  
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Filed: July 12, 2001  
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**REMARKS**

Claims 26-35 were pending in the subject application. By this Amendment, applicants canceled claims 27 and 32 without disclaimer or prejudice to applicants' right to pursue the subject matter of these claims in the future and have amended claims 26, 28-31, and 33-35 to specify that the antibody of the claimed methods is an anti-PM1 monoclonal antibody. Support for these amendments may be found in the specification *inter alia* at page 60, lines 3-13. Accordingly, applicants maintain that these amendments do not raise any issue of new matter. Applicants respectfully request that the Examiner enter this Amendment. Upon entry of this Amendment, claims 26, 28-31, and 33-35 as amended will be pending and under examination.

**Rejection under 35 U.S.C. §112, First Paragraph**

The Examiner rejected claims 26-35 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner alleged that the claims encompass a large genus of poorly defined monoclonal antibodies. The Examiner further alleged that the disclosure fails to provide any guidance pertaining to the molecular determinants modulating NSI/SI-Env mediated events or the structure of the claimed monoclonal antibodies.

In response, applicants respectfully traverse the Examiner's ground of rejection. Nevertheless, without conceding the correctness of the Examiner's rejection, applicants have herein amended claims 26, 28-31, and 33-35 to specify that the antibody of the claimed methods is an anti-PM1 monoclonal antibody.

Applicants' invention as now claimed provides a method of specifically inhibiting fusion of an HIV-1 envelope glycoprotein<sup>+</sup> cell with a CD4<sup>+</sup> cell that fuses with such HIV-1 envelope glycoprotein<sup>+</sup> cell, which comprises contacting the CD4<sup>+</sup> cell with an anti-PM1 monoclonal antibody

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which (1) inhibits HIV-1 envelope glycoprotein mediated membrane fusion of HeLa-env<sub>JRFL</sub> to a PM1 cell, but (2) does not inhibit HIV-1 mediated membrane fusion between HeLa-env<sub>LAI</sub> to a HeLa-CD4<sup>+</sup> cell, so as to thereby inhibit fusion of an HIV-1 envelope glycoprotein<sup>+</sup> cell with a CD4<sup>+</sup> cell.

Applicants' invention further provides a method of inhibiting infection of a CD4<sup>+</sup> cell by HIV-1 which comprises contacting the CD4<sup>+</sup> cell with an anti-PM1 monoclonal antibody that (1) inhibits HIV-1 envelope glycoprotein mediated membrane fusion of HeLa-env<sub>JR-FL</sub> to a PM1 cell, but (2) does not inhibit HIV-1 envelope glycoprotein mediated membrane fusion of HeLa-env<sub>LAI</sub> to a HeLa-CD4<sup>+</sup> cell, so as to thereby inhibit infection of the CD4<sup>+</sup> cell by HIV-1.

Applicants maintain that the structural characteristics of an antibody are well known in the art, so that one of skill in the art would easily understand the structure of the antibody recited in the methods now being claimed. In addition, applicants maintain that the genus of antibodies as now claimed provides for antibodies which have binding specificity to a PM1 cell. Applicants maintain that this functionally identifies the claimed antibody and provides sufficient support and an adequate disclosure for the genus of antibodies of the methods as now claimed.

Applicants further maintain that the specification discloses monoclonal antibodies PA-3, PA-5 and PA-7, which inhibit fusion of HeLa-env<sub>JR-FL</sub> to a PM1 cell (see page 60, lines 13-16 and Table 3), but which do not inhibit fusion of HeLa-env<sub>LAI</sub> to a HeLa-CD4<sup>+</sup> cell (see Table 3). In addition, as described on page 61, Table 3 in the specification, PA-3, PA-5 and PA-7 did not inhibit fusion of HeLa-env<sub>LAI</sub> to HeLa-CD4<sup>+</sup> cells (i.e. value is 0). The HeLa-env<sub>JR-FL</sub> and HeLa-env<sub>LAI</sub> cell lines used in the RET assay disclosed in the application are indicators of the fusion activity of macrophage-tropic and T cell-tropic HIV-1 strains, respectively (see the specification at, *inter alia*, page 52, lines 11-33 and pages 57-59). Accordingly, applicants maintain that the specification discloses examples of the anti-PM1 monoclonal antibody as recited in the claimed methods.

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In view of the preceding remarks, applicants maintain that the subject specification provides a written description sufficient to comply with the requirements of 35 U.S.C. §112, first paragraph. Accordingly, applicants maintain that the Examiner's ground of rejection has been overcome, and request allowance of claims 26, 28-31, and 33-35 as amended herein.

**Obviousness-Type Double Patenting Rejection**

The Examiner rejected claims 26-35 on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 1-8 of U.S. Patent No. 7,118,859.

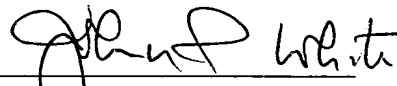
In response, applicants respectfully traverse this obviousness-type double patenting rejection. Applicants maintain that if upon entry of this Amendment, the pending claims are otherwise deemed allowable, applicants will consider whether filing a Terminal Disclaimer is appropriate.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

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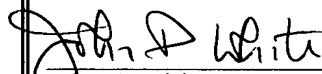
No fee, other than the enclosed \$525.00 fee for a three-month extension of time and the \$405.00 fee for filing a RCE, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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John P. White Date  
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